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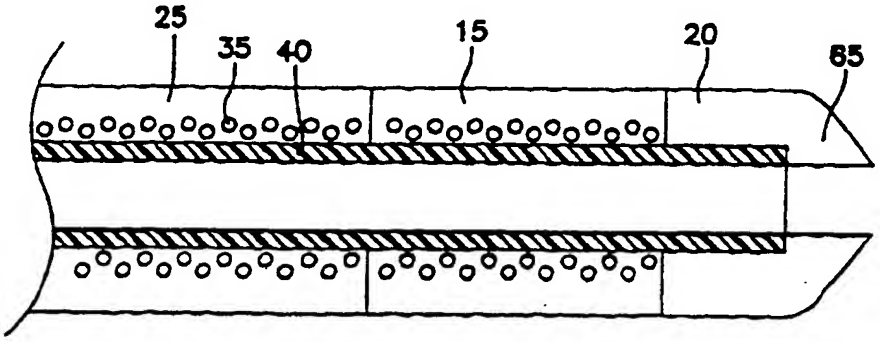


(57) Abstract

The present invention comprises a catheter and method of manufacture. The catheter includes an elongated core having a unitary lubricous liner and a reinforcement means. The lubricous liner defines at least one lumen. The lubricous liner has the reinforcement means over its outer diameter and fused to the lubricous liner. The reinforcement means terminates proximal to the distal end of the lubricous liner. The catheter also has an elongated shaft tube which defines a shaft tube lumen. The shaft tube lumen is sized to receive the core, the core which extends longitudinally through the shaft tube lumen. The shaft tube is fused to the core. The catheter also has an elongated transition tube which defines a transition tube lumen. The transition tube lumen is sized to receive the core which extends longitudinally through the transition tube lumen. The distal end of the shaft tube is fused to the proximal end of the transition tube. The transition tube is made of softer material than the shaft tube and is fused to the core. The catheter further includes an elongated tip tube made of softer material than the transition tube. The tip tube defines a tip tube lumen sized to receive the core which extends longitudinally throughout the tip tube lumen. The distal end of the transition tube is fused to the proximal end of the tip tube. The tip tube is fused to the core distal to the distal end of the reinforcement means, the distal end of the tip tube forming a rounded edge which overlaps the distal end of the lubricous liner by about .5 mm such that the distal end of the lubricous liner is not exposed.

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# IMPROVED METHOD OF SOFT TIP FORMING

## Field of the Invention

The present invention relates to catheters, and more particularly, to a method of soft tip attachment.

## Background of the Invention

Catheters are tube-like members inserted into the body for diagnostic or therapeutic reasons. One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of cholesterol fats or atherosclerotic plaque. Catheters must have sufficient stiffness to be pushed through vessels as well as sufficient rigidity to provide a high degree of torsional control. Stiffness or rigidity in the catheter tip poses the danger of puncturing or otherwise damaging a vessel as it twists through the vascular system. It is therefore desirable for catheters to have a soft or flexible distal tip. Examples of such soft tip catheters are known in the art.

The trend toward catheters with larger inside diameters and softer distal tip segments results, however, in a substantially weaker bond between the soft tip and the distal catheter shaft because of the thinner wall thickness and lower tensile strength of the softer materials. The following methods of tip attachment are known in the art.

Soft tips are often attached by means of a lap joint or butt joint at the distal end of the catheter body where the soft tip has been fused or welded to the catheter body. A butt joint or lap joint is undesirable because they create a stress concentration area at the distal end of the catheter shaft in a plane perpendicular to the longitudinal axis of the catheter shaft. The effect of this stress concentration is an low bond strength between the catheter shaft and the soft tip when the wall thickness of the catheter shaft is less than 0.3 mm.

U.S Patent No. 4,596,563 to **Pande** for a "Thin-Walled Multi-Layered Catheter Having a Fuseless Tip" discloses a two layered tubular body having a rigid inner sheath and a flexible outer sheath. The tip portion is fuseless with respect to the rest of the catheter, the tip portion being an integral extension of the flexible outer sheath that is formed over a gap between lengths of the rigid inner sheath.

U.S Patent No. 4,636,346 to **Gold** et al for a "Preparing Guiding Catheter" discloses a three-layered tubular body having a lubricous inner sheath defining a lubricous guiding lumen, a rigid intermediate sheath and a flexible outer sheath. The distal tip portion has a similar construction but from which the rigid intermediate sheath is omitted. Col. 5, lines 12 - 20 discloses a tip portion that may be an initially separate member affixed to the elongated tubular body 22 by suitable means, such as by heating, by other energy sources, and/or by adhesives or the like. Such assembly can be assisted by the use of a length of shrinkable tubing that is placed over the joint location prior to and during the assembly operation in order to enhance the smoothness and strength of the joint. It is an object of the invention to not require adding any braiding or strands of strengthening material.

U.S Patent No. 4,863,442 to **DeMello** et al for a "Soft Tip Catheter" discloses a tubular body with a wire-braided Teflon® core and a polyurethane jacket. The distal end of the jacket is removed from the core, and a soft polyurethane tip is applied to the core over the region where the jacket has been removed. The tip overlaps the core for approximately two millimeters and extends distally approximately two millimeters beyond the distal end of the core. The tip may be applied to the core as a separate tube bonded to it or be built up on the core by repeatedly dipping the tip in a polyurethane slurry, or be molded onto the distal end of the core. An embodiment at col. 5, lines 30 - 39 discloses a sleeve of shrink film 64 placed over the polyurethane tube 40 with the distal end of the jacket 18 and overlapping the shoulder 34. With the sleeve of shrink film 64 in place as shown in Fig. 2G, the distal end of the assembly is heated to a temperature and for a time sufficient to cause the soft polyurethane tube 40 to flow and fill the gap 46 along with any other gaps which may exist between it and the shoulder 34, outer surface 36 of the core 16, and the outer surface 54 of the mandrel 50.

U.S Patent No. 5,254,107 to **Soltesz** for a " Catheter Having Extended Braid Reinforced Transitional Tip" discloses an embodiment in col. 4, lines 34 - 41 wherein an inner tubular plastic layer 22 defines the inner diameter of the catheter, and which extends through the first and second sections 16, 18, but not

through third tip section 20. Inner tubular layer 22 may be made of PTFE. A braided stainless steel fiber tubular member 24 surrounds inner plastic layer 22.

In the commonly owned, copending application of Brin et al. for "Improved Method of Catheter Segment Attachment" U.S. application serial number 08/236,766 the distal end of the catheter consists of three segments, the transition tubing which is attached to the shaft, the soft tip tubing which is attached to the transition tubing, and the "plug" tubing which is attached to the soft tip tubing for ease of handling during manufacture and into which a support mandrel is inserted. All three segments are surrounded by a tube of heat shrink. The heat source acts upon the transition tubing with the heat being propagated to the soft tip tubing. After assembly, the plug tubing and part of the soft tip tubing are trimmed off. The catheter shaft is comprised principally of three layers: a lubricous TEFLON® liner, a composite layer of wire braid and polymer, and an outer jacket polymer. The wire braid and TEFLON® liner do not extend into the transition tubing or into the soft tip tubing.

An object of the invention is to create a guiding catheter soft tip with wall thickness less than 0.3 mm which provides improved bond strength to the catheter shaft joints, and in particular, the joint between the soft tip segment and the segment proximal to the soft tip.

Another object of the invention is to provide a lubricous inner lumen throughout the catheter body including throughout the soft tip while shielding the lubricous liner from contact with the vessel wall and while maintaining a curved contour at the distal end.

Another object of the invention is to minimize the length of the unreinforced section of the soft tip to avoid devices snagging during deployment.

## SUMMARY OF THE INVENTION

The present invention comprises a catheter and method of manufacture. The catheter includes an elongated core having a unitary lubricous liner and a reinforcement means. The lubricous liner defines at least one lumen. The lubricous liner has the reinforcement means over the its outer diameter and fused to the lubricous liner. The reinforcement means terminates proximal to the distal end of the lubricous liner. The catheter also has an elongated shaft tube which defines a shaft tube lumen. The shaft tube lumen is sized to receive the core, the

core which extends longitudinally through the shaft tube lumen. The shaft tube is fused to the core. The catheter also has an elongated transition tube which defines a transition tube lumen. The transition tube lumen is sized to receive the core which extends longitudinally through the transition tube lumen. The distal end of the shaft tube is fused to the proximal end of the transition tube. The transition tube is made of softer material than the shaft tube and is fused to the core. The catheter further includes an elongated tip tube made of softer material then the transition tube. The tip tube defines a tip tube lumen sized to receive the core which extends longitudinally throughout the tip tube lumen. The distal end of the transition tube is fused to the proximal end of the tip tube. The tip tube is fused to the core distal to the distal end of the reinforcement means, the distal end of the tip tube forming a rounded edge which overlaps the distal end of the lubricous liner by about .5 mm such that the distal end of the lubricous liner is not exposed.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is the preassembly plan view of the distal end of a guiding catheter prior to the outer jacket molding process;

FIGURE 2 is the molded assembly of Fig. 1;

FIGURE 3 is the is a cross-sectional view of the distal tip of the molded assembly of Fig. 2;

FIGURE 4 is the plan view of the distal end of a guiding catheter prior to the soft tip formation process;

FIGURE 5 is the molded assembly of fig 4; and

FIGURE 6 is a cross-sectional view of the distal tip of the molded assembly of Fig. 5.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention addresses the problem created by the trend toward catheters with larger inside diameters and softer distal tip segments. Soft tip guiding catheters are desirable because the gentle ostial engagement is less traumatic. Soft tips provide a coaxial fit in all anatomies to allow for improved device delivery by maintaining a rounded tip shape which adapts to different ostial take-offs. Larger lumens are desirable because they permit more dye flow and offer more device delivery options. The trend toward catheters with larger inside

diameters and softer distal tip segments results in a substantially weaker bond between the soft tip and the distal end of the catheter shaft due to thin catheter shaft walls of less than 0.3 mm and to the lower tensile strength of the softer tip materials. Applicants address the problem of bond strength between segments and that of achieving greater lumen lubricity by extending a unitary liner throughout the shaft, transition tubing and soft tip segments, the liner being made of a fluoropolymer such as TEFLON® from E.I. Du Pont de Nemours & Company, Wilmington, Delaware. TEFLON® which is a form of polytetrafluoroethylene (PTFE). To maintain a soft tip, the TEFLON® is shielded from contact with the vessel wall by using heat shrink tubing in a heating process to draw the distal end of the soft tip material over the exposed TEFLON® liner.

Manufacturing applicant's thin wall guiding catheter consists of two major processes, outer jacket molding and soft tip formation. Fig. 1 - 3, represent applicant's assembly for molding the outer jacket to the braided TEFLON® core material. Figs. 4 -6 represent applicant's assembly for forming the soft tip.

Referring to Fig. 3 which depicts the molded assembly, the shaft of the thin wall guiding catheter for outer jacket molding is assembled as follows. Slide the TEFLON® liner 40 over a stainless steel mandrel 30 (not shown in Fig. 3). The mandrel 30 may optionally be TEFLON® coated. Next, braid wire 35 over the TEFLON® liner 40. The mandrel 30 has an outer diameter of approximately .001 inch less than the inner diameter of the TEFLON® liner 40. The mandrel 30 is used for support. TEFLON® beading could be alternatively used for support. After the catheter shaft is assembled, the support will be removed. The TEFLON® liner 40 provides a lubricous surface which aids device delivery by providing a low friction interface. This is especially important for the smooth passage of large, non-balloon devices which may not conform as readily to guiding catheter curves. The TEFLON® 40 enhances device delivery with less device "capture" while ensuring circumferential integrity.

Wire 35 is braided by means of a conventional braiding machine over the TEFLON® liner 40 as shown in Fig. 3. The wire braid 35 is advantageous because it reinforces and supports the large lumen for thin wall guiding catheters. The wire braid 35 is a 16 strand stainless steel braid which runs the length of the catheter and is trimmed a few millimeters proximal to the distal end of the

TEFLON® liner 40. The distal end of the wire braid 35 is then adhesively bonded to the TEFLON® liner 40. Those skilled in the art would recognize that other reinforcement means could be used, such as carbon fibers.

The catheter shaft comprises a plurality of segments overlying the wire braid 35 and TEFLON® liner 40. These segments, the 72D shaft tubing 25, the 55D transition tubing 15, the 35D soft tip tubing 20 and the 72D plug tubing 45 are made from PEBAX®. Although other polymers can be found in a suitable durometer range, PEBAX®, a polyether block amide copolymer obtainable from the Elf Atochem Corporation, Philadelphia, PA, is preferable in catheter design because it is an elastomer, has low moisture absorbance, offers long term stability of material properties, provides high tensile strength and can be processed at temperatures in the 400 degree F range as required by commonly available extrusion equipment. The segments are abutted as follows.

The shaft tubing 25 is made from PEBAX® in the hardness range of Shore durometer D65-D75 and preferably 72D. The transition tube 15 may have a hardness range of Shore durometer 50D - 60D and preferably 55D. Taper the end of the 72D Pebax® shaft tubing 25 using an outside taper cutting tool. Cut a Shore 55D Pebax® transition tube 15 to 3.7 cm in length and taper the end using an inside taper cutting tool. The 3.7 cm length was chosen from an acceptable range of 2 cm to 18 cm based on anatomical considerations, as 4 cm is the average width of the aortic root. Slide the untapered end of the Shore 72D shaft tubing over the braided TEFLON® liner 40 from its distal end. Next slide the 55D transition tubing 15 onto the mandrel 30 and over the braided TEFLON® liner 40 from its distal end such that the tapered end of the 55D transition tubing 15 mates with the tapered end of the 72D shaft tubing. The 72D shaft tubing 25 and 55D transition tubing 15 can be tapered because the materials are stiff enough to retain their shape when melted. The material at the joint will blend better when the mating ends are tapered yielding better bond strength than would an abutted end as there is greater surface area over which to blend the materials. The 55D transition tubing 15 may have a wall thickness of .013 inches (.033 cm) and an inner diameter ranging from a minimum of .078 inches for 6F to a maximum of .126 inches for 10F. The wire braid 35 extends through the 55D transition tubing 15 to offer better kink resistance and ends preferably at

approximately the proximal end of the 35D soft tip tubing 20 to permit maximum flexibility in the soft tip 20. The wire braid 35 can stop from 2 - 3 mm proximal to the 35D soft tip and still provide sufficient reinforcement but should not extend more that 1/3 of the length of the soft tip 20 into the proximal end of 35D soft tip 20 to provide optimal soft tip 20 flexibility. At least one inch of the mandrel 30 should extend beyond the distal end of the 35D tip tube 20 for ease of handling.

A softer durometer material is used for the soft tip 20 than for the transition tubing 15 to give the distal end more flexibility; this aids in tip placement. The soft tip 20 may be in the range of Shore 25D to 40D and preferably 35D. The 35D tip tube 20 can be made of Pebax®. The 35D tip tube 20 preferably has a length of approximately 1 cm prior to trimming and a wall thickness of .013 inches (.33 cm) and an inner diameter ranging from a minimum of .078 inches for 6F to a maximum of .126 inches for 10F. The 1 cm length was chosen for handling convenience during the trimming process. Because the TEFLON® liner 40 extends throughout all three segments (the 72D shaft tubing 25, the 55D transition tubing 15 and the 35D soft tip tubing 20) lubricity is improved and device delivery enhanced. Furthermore, the unitary TEFLON® liner 40 extending throughout the shaft improves joint strength between the 72D shaft tubing 25 and the 55D transition tubing 15 as well as between the 55D transition tubing 15 and the 35D soft tip tubing 20.

Slide a Shore 72D Durometer plug tube 45 of approximately 1 cm onto the distal end of the mandrel 30 until it butts against the distal edge of the 35D soft tip tubing. The plug tube 45 can be made of Pebax®. Leave approximately 15.2 cm or 6 inches of mandrel 30 extending distally beyond the assembly for handling convenience.

Slide a segment of TEFLON® fluorinated ethylene propylene (FEP) heat shrink tubing 10 over the entire assembly with approximately 1 cm of heat shrink extending beyond the distal end of the 72D plug tube 45 and over the mandrel 30. Heat shrink tubing such as that from Zeus Industrial can be used. Ensure that the joint between the 55D transition tubing 15 and the 35D soft tip tubing 20 is approximately 15.9 cm from the distal end of the mandrel 30 for handling convenience.

The outer jacket is molded when the heat shrink 10 is heated by any suitable means to fuse the segments. For example, radiant heating or conduction heating can be used. Heat shrink tubing 10 contraction, when coupled with heating the tip materials causes them to expand, resulting in the materials blending and flowing into one another. A lap joint between the materials is produced. Those skilled in the art would recognize that different time and temperature combinations would be suitable as time and temperature vary inversely.

To achieve bonding, the time and temperature selected must be sufficient to render the materials flowable. Temperatures which are too high will result in a brittle product. Temperatures which are too low will result in improper fusion. A suitable convection oven temperature for outer jacket molding includes 185 degrees centigrade. This temperature should be maintained for approximately 7 to 8 minutes depending on the size catheter being molded. Those skilled in the art would recognize that different time and temperature combinations would be suitable as time and temperature vary inversely. Referring to Fig. 2, the heat source causes the catheter shaft tubing 25, the transition tubing 15, the soft tip tubing 20 and the plug tubing 45 to become flowable while the heat shrink 10 contracts both radially and longitudinally thereby colliding all segments. This results in a lap joint between each segment.

The heat shrink tubing 10 is removed with a razor blade and the molded tip assembly is cut to length. The distal end is trimmed back to a point within the 35D soft tip tubing to result in a tip length of 2.5 mm distal to the 55D transition tubing 15. Lengths that are much longer are undesirable because the soft tip 20 is not structurally rigid and may fold back upon itself and cause difficulty with device passage. The mandrel 30 is removed from the inside of the now bonded assembly. Fig. 3 shows the enlarged longitudinal cross section of the distal end portion of the molded assembly of Fig. 2.

After outer jacket molding, the soft tip 20 is formed. Extending the TEFLON® liner 40 to the distal end of the soft tip tubing improves lubricity. The unitary liner also improves joint strength between the 35D soft tip 20 and the 55D transition tubing 15 but results in a tip that is too sharp. To remedy this, a soft tip 20 tapered distal edge which overlaps and shields the TEFLON® liner 40 and can

be created as follows to blunt the sharp TEFLON® liner 40. See Figure 4. Taking the assembly from the outer jacket molding process, insert a mandrel 30 into the distal end of the assembly such that at least 1 inch protrudes from the distal tip of the assembly. Apply approximately 2 inches of heat shrink tubing 110 over the distal end of the assembly such that the heat shrink 110 extends one-half to one centimeter beyond the proximal and distal ends of the soft tip 20 material as seen in Fig. 4. Next insert the assembly (until the soft tip 20 material can no longer be seen) into a preheated forming die, as for example, a hot block consisting of a brass cylinder with and external band heater. Dwell at a temperature of 400 degrees F. This temperature is maintained for approximately 7 to 8 seconds depending on the size catheter being molded. Those skilled in the art would recognize that different time and temperature combinations would be suitable as time and temperature vary inversely. Remove the assembly from the forming die. The heat shrink 110 will have contracted about the soft tip 20 as seen in Fig. 5. After the assembly has cooled for at least 10 seconds, remove the heat shrink tubing 110. Remove the supporting mandrel 30. As seen in Fig. 6, the contraction of the heat shrink 110 will have caused the 35D soft tip 20 material to flow and draw the distal end of the 35D soft tip 20 approximately .5 mm over the distal end of the TEFLON® liner 40, thereby covering the exposed TEFLON® liner 40 by creating a somewhat radiused, overhanging edge 65.

Applicants reinforced soft tip 20 with an unreinforced rounded edge 65 is advantageous. A rounded edge 65 shielding the exposed TEFLON® liner 40 reduces trauma in body cavities. It is common to deliver such devices as balloon catheters, stents or atherectomy devices through guiding catheters. Having a short unreinforced soft tip edge 65 of .5 mm is advantageous because it diminishes the likelihood of devices snagging during device delivery. Soft tips on guide catheters deflect easily, especially if they are unreinforced. Unreinforced soft tips of two mm or more increase the likelihood of devices snagging during delivery. Unreinforced soft tips of less than 1 mm reduce the likelihood of a device snagging. Applicant's soft tip 20 having the TEFLON® liner 40 throughout the soft tip 20 provides increased stiffness which further avoids devices snagging during deployment.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A catheter comprising:

an elongated core having a unitary lubricous liner and a reinforcement means, the lubricous liner having a distal end, an outer diameter and a proximal end, the lubricous liner defining at least one lumen, the lubricous liner having the reinforcement means over the outer diameter and fused to the lubricous liner, the reinforcement means terminating proximal to the distal end of the lubricous liner;

an elongated shaft tube having a distal end and a proximal end, the shaft tube defining a shaft tube lumen, the shaft tube lumen sized to receive the core, the core extending longitudinally through the shaft tube lumen, the shaft tube being fused to the core;

an elongated transition tube having a distal end and a proximal end, the transition tube defining a transition tube lumen, the transition tube lumen being sized to receive the core, the core extending longitudinally through the transition tube lumen, the distal end of the shaft tube being fused to the proximal end of the transition tube, the transition tube being fused to the core, the transition tube being made of softer material than the shaft tube; and

an elongated tip tube having a distal end and a proximal end, the tip tube being made of softer material then the transition tube, the tip tube defining a tip tube lumen, the tip tube being sized to receive the core, the core extending longitudinally through the tip tube lumen, the distal end of the transition tube being fused to the proximal end of the tip tube, the tip tube being fused to the core distal to the distal end of the reinforcement means, the distal end of the tip tube forming a unitary rounded edge which curves over the distal end of the lubricous liner such that the distal end of the lubricous liner is not exposed.

2. The catheter of claim 1 wherein the shaft tube is made from a polymer material exhibiting a hardness in the range of Shore durometer 65D to 75D.

3. The catheter of claim 1 wherein the transition tube is made from a polymer material exhibiting a hardness in the range of Shore durometer 50D to 60D.

4. The catheter of claim 1 wherein the tip tube is made from a polymer material exhibiting a hardness in the range of Shore durometer 25D - 40D.

5. The catheter of claim 1 wherein the shaft tube distal end and the transition tube proximal end have complimentary tapers.

6. The catheter of claim 1 wherein the lubricous liner is made of a fluoropolymer material.

7. The catheter of claim 1 wherein the shaft tube, or transition tube or the tip tube may be made from a polyether block amide copolymer material.

8. The catheter of claim 1 wherein the tip tube is fused to the core between 2 - 3 mm distal to the distal end of the reinforcement means.

9. The catheter of claim 1 wherein the tip tube is fused to the core such that the distal end of the reinforcement means extends under the proximal end of the tip tube for not more than one third of the length of the tip tube.

10. The catheter of claim 1 wherein the transition tube has a length of approximately 3.7 cm.

11. The catheter of claim 1 wherein the tip tube has a length of approximately 2.5 mm.

12. The catheter of claim 1 wherein the rounded edge extends approximately .5 mm distally beyond the lubricous liner.

13. The catheter of claim 1 wherein the reinforcement means comprises a wire braid.

14. A method of manufacturing a catheter comprising the steps of:

providing a catheter subassembly having a core comprising a lubricous liner and a reinforcement means, the lubricous liner having a distal end, an outer diameter and a proximal end, the lubricous liner defining at least one lumen, the lubricous liner having the reinforcement means over the outer diameter and fused to the lubricous liner, the reinforcement means terminating proximal to the distal end of the lubricous liner;

placing an elongated shaft tube over the proximal end of the core;

placing an elongated transition tube of softer material than the shaft tube over the distal end of the core and abutting the distal end of the shaft tube to the proximal end of the transition tube;

placing an elongated tip tube of softer material then the transition tube over the distal end of the core and abutting the distal end of the transition tube to the proximal end of the tip tube such that the distal end of the reinforcement means ends approximately at the proximal end of the tip tube;

placing a tube of heat shrink over at least a portion of the shaft tube, transition tube and tip tube;

heating the heat shrink to fuse the core to the shaft tube, to fuse the transition tube and tip tube, to fuse the distal end of the shaft tube to the proximal end of the transition tube and to fuse the distal end of the transition tube to the proximal end of the tip tube;

removing the heat shrink;

trimming off a portion of the soft tip tubing;

placing a tube of heat shrink over the tip tube such that the heat shrink extends beyond the distal end and beyond the proximal end of the tip tube; and

applying heat to the tip tube causing the tip material to flow and the heat shrink to draw the distal end of the tip tube over the distal end of the lubricous liner forming a unitary rounded edge covering the lubricous liner.

15. The method of claim 14 wherein the shaft tube distal end and the transition tube proximal end have complimentary tapers.

16. The method of claim 14 wherein the tip tube has a length of approximately 2.5 mm.

17. The method of claim 14 wherein the transition tube has a length of approximately 3.7 cm. mm.

18. The method of claim 14 wherein the distal end of the reinforcement means ends not less then approximately 2-3 mm proximal to the proximal end of the tip tube and not more then approximately 1/3 of the length of the tip tube from the proximal end of the tip tube.

19. The method of claim 14 wherein the reinforcement means comprises a wire braid.

20. The method of claim 14 wherein the transition tube is made from a polymer material exhibiting a hardness in the range of Shore durometer 50D to 60D.

21. The method of claim 14 wherein the tip tube is made from a polymer material exhibiting a hardness in the range of Shore durometer 25D - 40D.

22. The method of claim 14 wherein the rounded edge extends approximately .5 mm distally beyond the lubricous liner.

23. A method of manufacturing a catheter comprising the steps of:

providing a catheter having a lubricous liner extending longitudinally throughout the catheter, the lubricous liner defining at least one lumen;

placing a tube of heat shrink over the distal end of the catheter such that the heat shrink extends beyond the distal end of the catheter; and

applying heat to the heat shrink causing the material at the distal end of the catheter to flow and the heat shrink to draw the distal end of the catheter over the distal end of the lubricous liner thereby forming a unitary rounded edge covering the lubricous liner.

24. The method of claim 14 wherein the rounded edge extends approximately .5 mm distally beyond the lubricous liner.

25. The method of claim 23 wherein the rounded edge extends approximately .5 mm distally beyond the lubricous liner.

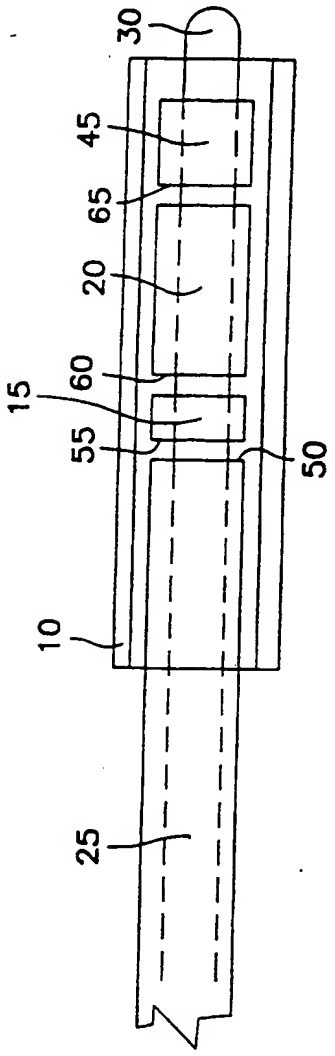


FIG. 1

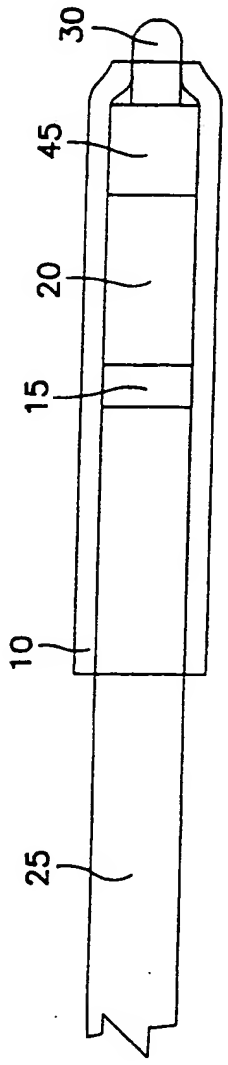


FIG. 2

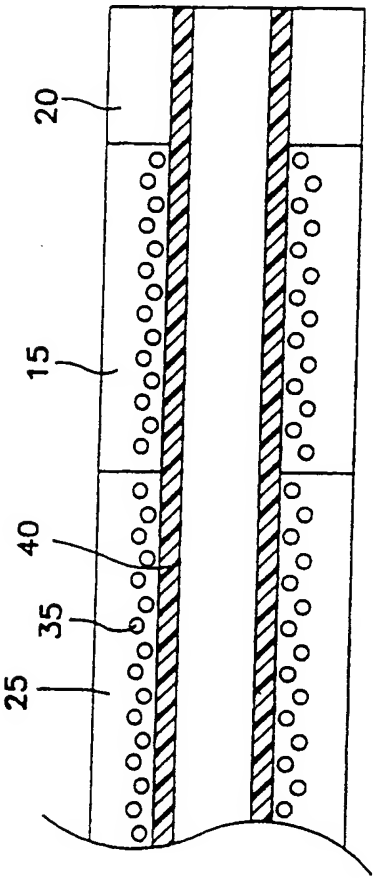


FIG. 3

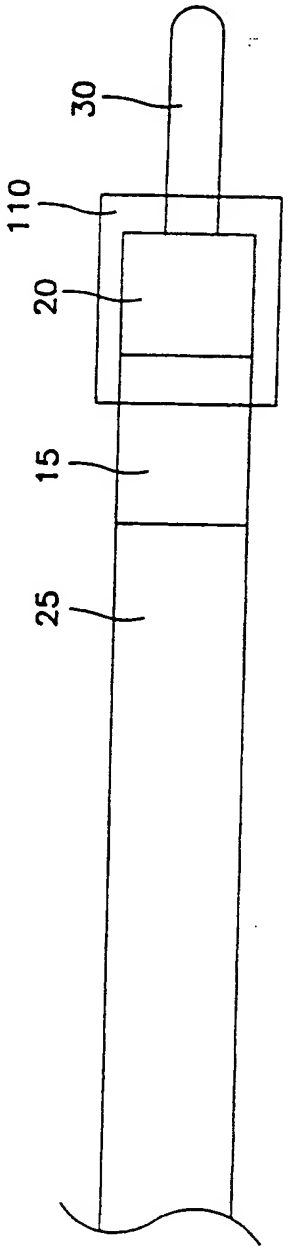


FIG. 4

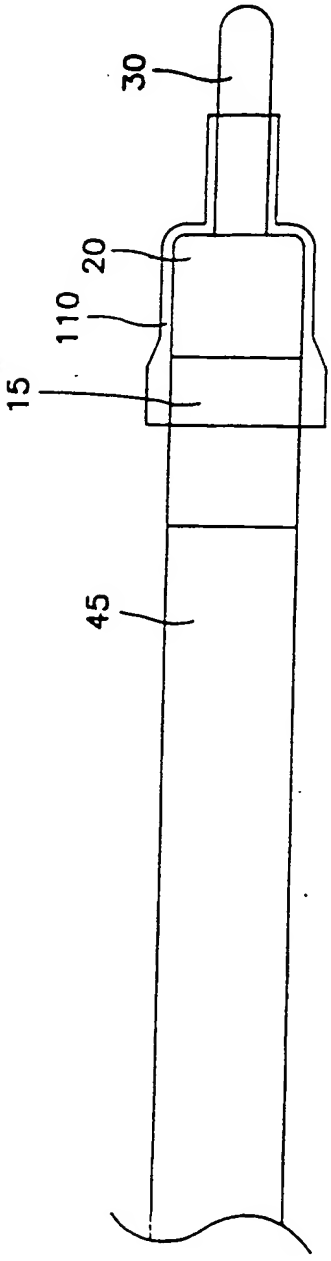


FIG. 5

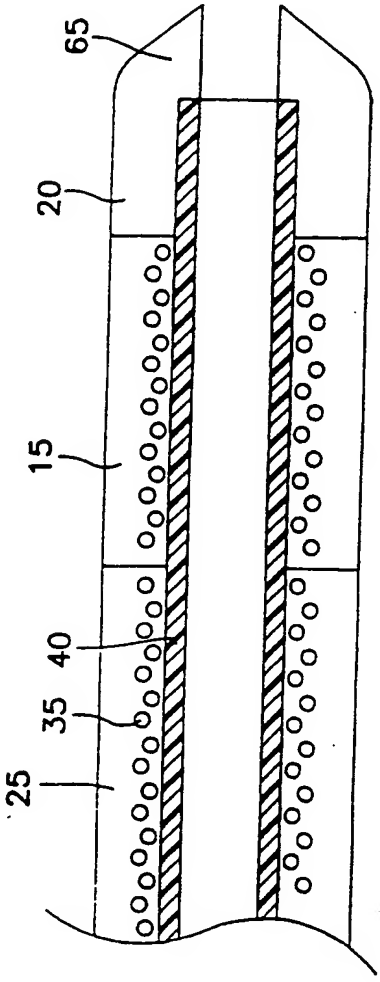


FIG. 6

# INTERNATIONAL SEARCH REPORT

Internation pplication No
PCT/US 95/16745

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US,A,5 254 107 (SOLTESZ) 19 October 1993<br>cited in the application<br>see the whole document<br>--- | 1,2,5,6,<br>13-15,19 |
| A | US,A,4 863 442 (DEMELLO) 5 September 1989<br>cited in the application<br>see column 4, line 27 - column 5, line 63;<br>figures<br>--- | 1,8,14,<br>23 |
| A | EP,A,0 517 075 (ADVANCED CARDIOVASCULAR<br>SYSTEMS) 9 December 1992<br>see abstract; figures<br>--- | 1,14 |
| A | EP,A,0 520 692 (COOK) 30 December 1992<br>see abstract; figures<br>--- | 1,14,23 |
| | -/-- | |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 21 May 1996 | 04.06.96 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. ( + 31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax ( + 31-70) 340-3016 | Kousouretas, I |

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US 95/16745

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|
| US-A-5254107 | 19-10-93 | NONE | | |
| US-A-4863442 | 05-09-89 | AU-B- | 621548 | 19-03-92 |
| | | AU-B- | 2067488 | 16-02-89 |
| | | EP-A- | 0303487 | 15-02-89 |
| | | JP-A- | 1068276 | 14-03-89 |
| | | JP-B- | 7002184 | 18-01-95 |
| EP-A-517075 | 09-12-92 | US-A- | 5234416 | 10-08-93 |
| | | CA-A- | 2070452 | 07-12-92 |
| | | JP-A- | 6086822 | 29-03-94 |
| EP-A-520692 | 30-12-92 | US-A- | 5221270 | 22-06-93 |
| | | AU-B- | 652254 | 18-08-94 |
| | | AU-B- | 1833492 | 07-01-93 |
| | | CA-A- | 2069807 | 29-12-92 |
| | | CA-A- | 2078201 | 29-12-92 |
| | | JP-A- | 7008563 | 13-01-95 |
| EP-A-555088 | 11-08-93 | US-A- | 5318032 | 07-06-94 |
| EP-A-334640 | 27-09-89 | US-A- | 5078702 | 07-01-92 |
| | | JP-A- | 1310666 | 14-12-89 |
| WO-A-9515780 | 15-06-95 | AU-B- | 7860994 | 27-06-95 |

# INTERNATIONAL SEARCH REPORT

International application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | EP,A,0 555 088 (DEVICES FOR VASCULAR INTERVENTION) 11 August 1993<br>see column 8, line 50 - column 9, line 40;<br>figure 3 | 1,14 |
| A | EP,A,0 334 640 (BAXTER) 27 September 1989<br>see abstract; figures | 1,23 |
| P,A | WO,A,95 15780 (SCHNEIDER) 15 June 1995<br>see the whole document | 1-7,13,<br>14 |